HANSA BIOPHARMA

Presentation
DNB Nordic-American Life Science Conference

New York City, December 5, 2019

Soren Tulstrup, President & CEO

Forward-looking statement

This presentation may contain certain forward-looking statements and forecasts based on our current expectations and beliefs regarding future events and are subject to significant uncertainties and risks since they relate to events and depend on circumstances that will occur in the future. Some of these forward-looking statements, by their nature, could have an impact on Hansa Biopharma's business, financial condition and results of operations [or that of its parent, affiliate, or subsidiary companies]. Terms such as "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statements. There are a number of factors that could cause actual results and developments to differ materially from those projected, whether expressly or impliedly, in a forward-looking statement or affect the extent to which a particular projection is realized. Such factors may include, but are not limited to, changes in implementation of Hansa Biopharma's strategy and its ability to further grow; risks and uncertainties associated with the development and/or approval of Hansa Biopharma's product candidates; ongoing clinical trials and expected trial results; the ability to commercialize imlifidase if approved; changes in legal or regulatory frameworks, requirements, or standards; technology changes and new products in Hansa Biopharma's potential market and industry; the ability to develop new products and enhance existing products; the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors.

The factors set forth above are not exhaustive and additional factors could adversely affect our business and financial performance. We operate in a very competitive and rapidly changing environment, and it is not possible to predict all factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results.

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Hansa Biopharma at a glance

Company background

- Founded 2007 with HQ in Lund, Sweden
- Sören Tulstrup, CEO – Ulf Wiinberg, Chairman
- 64 employees (~3/4 in R&D) at Sep 30, 2019
- Operations in Sweden, US & Europe
- Market cap: SEK ~6bn (USD ~600m) Oct, 2019
- Listed on Nasdaq OMX Stockholm (HSNA)

Leader in immunomodulatory enzymes for rare IgG-mediated diseases

- Imlifidase is a unique IgG antibody-cleaving enzyme
- Imlifidase has been studied in five clinical studies and published in peer-reviewed journals (e.g. New England Journal of Medicine and the American Journal of Transplantation)
- If approved, Imlifidase may have the potential to meet a large unmet need and transforming the lives of people with rare disease

Broad pipeline in transplantation and autoimmune diseases

- Lead indication in kidney transplantation in highly sensitized patients (MAA under review by EMA)
- Anti-GBM antibody disease (Phase 2)
- Antibody mediated kidney transplant rejection (AMR) (Phase 2)
- Guillain-Barré syndrome (Phase 2)
- NiceR - Recurring treatment in autoimmune disease, transplantation and oncology (Preclinical)
- EnzE – Cancer immunotherapy (Preclinical)

Key Financials

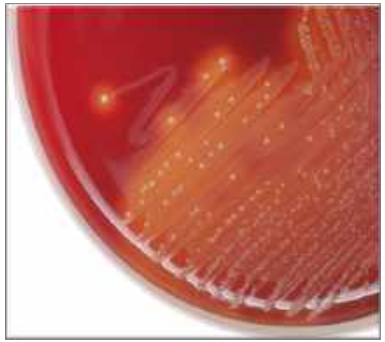
• Cash position	9m'19 SEK 680m
• Operating Cash Flow	9m'19 SEK -260m
• R&D cost	9m'19 SEK -135m
• Net Profit	9m'19 SEK -249m

…at Hansa Biopharma we envision a world where all patients with rare immunologic diseases can lead long and healthy lives...

Imlifidase – a novel approach to eliminate pathogenic IgG

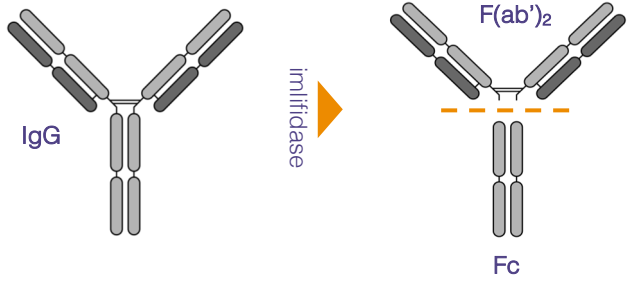
Origins from Streptococcus pyogenes

- Species of Gram-positive, spherical bacteria in the genus Streptococcus
- Usually known from causing a strep throat infection



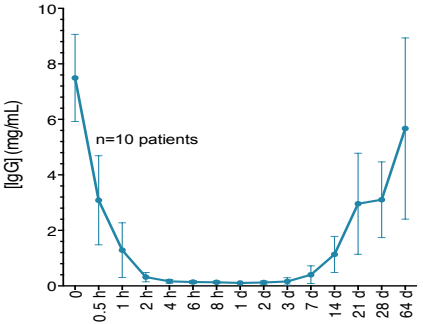
Imlifidase, a unique IgG antibody-cleaving enzyme

- Interacts with Fc-part of IgG with extremely high specificity
- Cleaves IgG at the hinge region, generating one $F(ab')_2$ fragment and one homo-dimeric Fc-fragment



Imlifidase inactivates IgG in 2 hours

- Rapid onset of action that inactivates IgG below detectable level in 2 hours
- IgG antibody-free window for approximately one week



Regulatory review with EMA is progressing as expected

Imlifidase in kidney transplantation

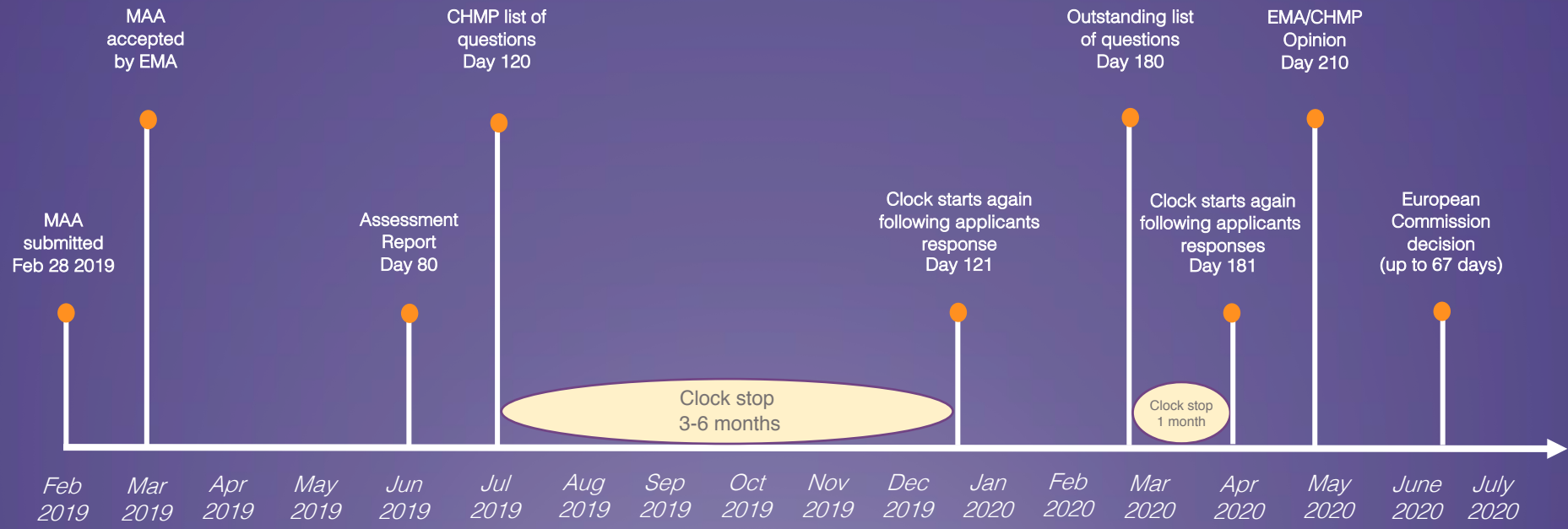
Europe (EMA)

- MAA for imlifidase accepted end of Feb'19; regulatory review progressing as expected
- Opinion from Committee for Medicinal Products for Human Use (CHMP) expected during the first half of 2020
- Decision by European Commission expected June/July 2020

U.S. (FDA)

- Follow-up meeting with the U.S. Food and Drug Administration scheduled for November 20, 2019 to discuss regulatory path forward in the U.S.
- Minutes from the meeting is expected by end of December

The EMA process towards marketing authorization



Focused launch strategy optimizes patient access to imlifidase

Strong outreach with limited footprint in EU

- Building awareness through MSL and Patient Advocacy
  - MSL organization established in key markets
  - MSLs educate KOLs and physicians at transplantation clinics
  - Reaching out to healthcare providers through Patient Advocacy
- A sequenced and focused launch strategy
  - In EU5, 70-80% of all kidney transplantations are performed at 15-20 centers in each EU5 country
  - Potential Initial launch in early launch countries in the second half of 2020 followed by second wave launch countries

Imlifidase may enable transplantation in highly sensitized kidney patients

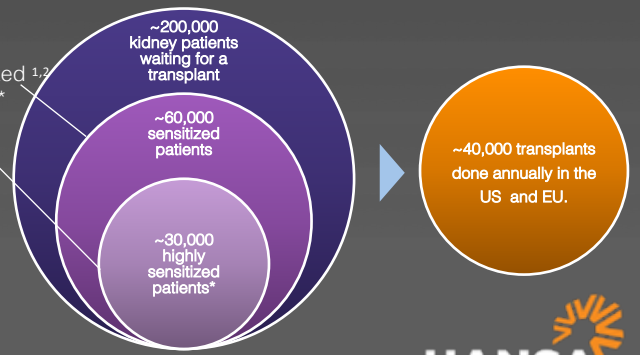
Creating equity for highly sensitized patients

- Allocation systems increase transplantation rates, however the rates for highly sensitized patients are still very low compared with average or non-sensitized patients
- If approved, imlifidase may potentially:
  - Complement allocation systems (e.g. KAS, Euro-transplant) to reduce time to transplant in highly sensitized patients
  - Reduce the need for antibody matching and give sensitized patients access to a larger pool of organs
  - Reduce the risk for co-morbidities and mortality associated with dialysis and waiting time
  - Increase transplant rates in highly sensitized patients
  - Help reduce the number of discarded kidneys (+1,000 donated kidneys are discarded in the U.S. alone every year[3])

Delilah, a 23 years old highly sensitized kidney transplant patient from California

U.S. + EU Kidney Transplant Waitlist Breakdown

>30% of waitlist patients are sensitized
- 15% moderately sensitized [1,2]
- 15% highly sensitized[1,2] *



*Patients with sensitivity above cPRA 80%

Source: The U.S. Department of Health and Human Services and .irodat.org

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[1] Jordan et al. British Medical Bulletin, 2015, 114:113–125
[2] Orandi et al. N Engl J Med 2016;374:940-50
[3] Organ Procurement and Transplantation Network (OPTN)
[4] Jordan et al. British Medical Bulletin, 2015, 114:113-125

Approximately 30% of patients on wait list are moderately or highly sensitized (10-15%)

Highly sensitized patients are difficult to match

- Causes of sensitization include

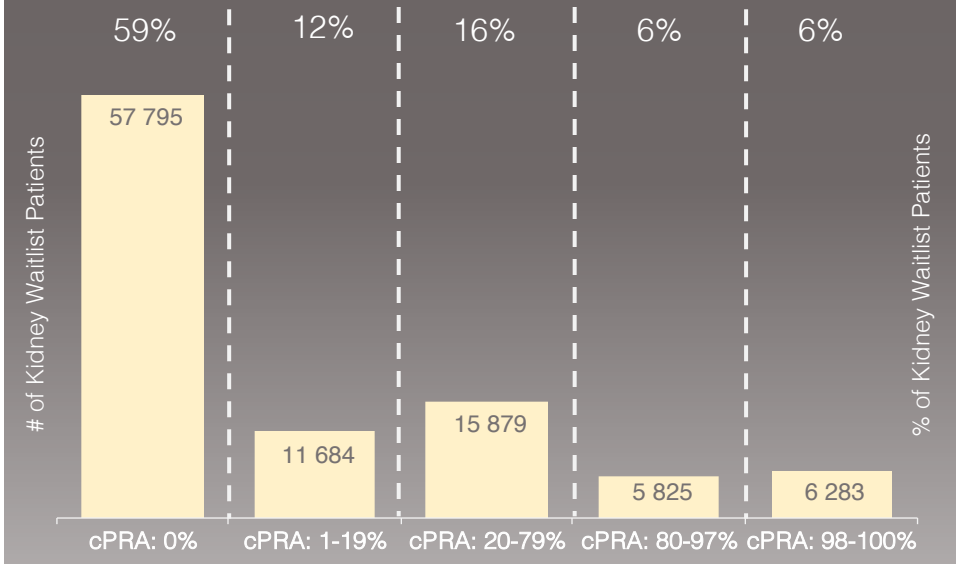
Pregnancy

Blood transfusion

Previous transplantations

- Calculated Panel Reactive Antibodies (cPRA) is a measure for HLA-sensitization
- Inability to match or effectively desensitize patients remains a barrier for transplant of highly sensitized patients
- Allocation Systems such as KAS and Eurotransplant relies on cPRA score to characterize patients for transplant

US Kidney Waitlist Patients by cPRA 2018



Source: Organ Procurement and Transplant Network, Advanced Report. Analysis as of September 25, 2018

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High unmet medical need in spite of updated Kidney Allocation System

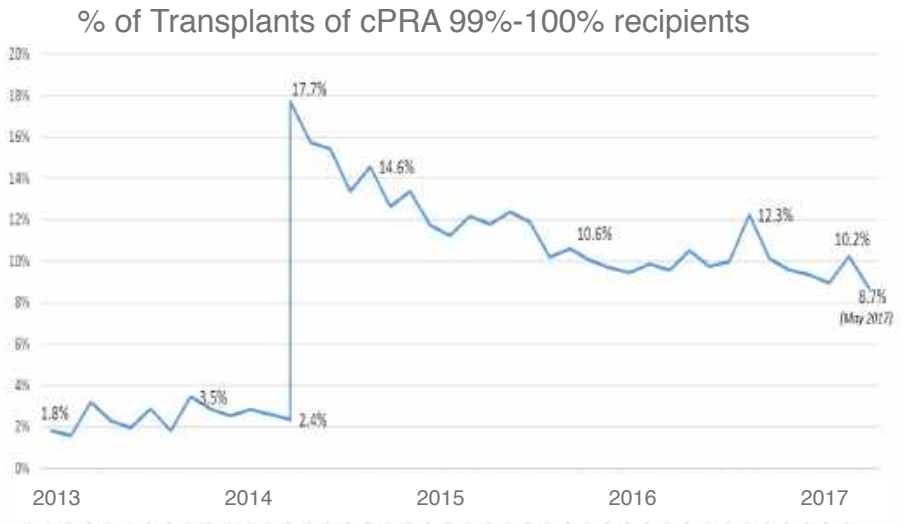
Imlifidase may potentially complement KAS

- The Kidney Allocation System (KAS) in U.S. was updated in 2014 to prioritize national allocation for highly sensitized patients
- Implementation initially resulted in a bolus effect; however a group of highly sensitized patients are still not helped due to lack of matched organs
- If approved, imlifidase may potentially complement allocation systems like KAS and Euro-transplant and reduce time to transplant in highly sensitized patients

"*We thought the KAS would be very good, but the experience was different. I don't think you can have a bureaucratic solution for an immunologic problem, we have to face that we do need drugs to deal not only with acute antibodies but also with the rebound.*"

Stanley Jordan M.D., Director Kidney Transplantation and Transplant Immunology at the Cedars-Sinai Medical Center in LA.

Significant number of highly sensitized patients remains on the waiting list post KAS



Source:
OPTN/UNOS
Darren Stewart, MS,
UNOS Research Department

Broad pipeline in transplantation and auto-immune diseases

Candidate / Projecting	Indication	Research/ Preclinical	Phase 1[1]	Pivotal program/ Phase 2	Marketing Authorization	Marketed	Next Anticipated Milestone
Imlifidase	Kidney transplantation in highly sensitized patients				*)		MAA review by EMA Follow-up meeting with FDA Nov 20, 2019
	Anti-GBM antibody disease						Complete enrollment
	Antibody mediated kidney transplant rejection (AMR)						Complete enrollment
	Guillain-Barré syndrome						Complete enrollment
NiceR	Recurring treatment in autoimmune disease, transplantation and oncology						Development of CMC process / Tox studies
EnzE	Cancer immunotherapy						Research phase

Completed Ongoing

[1] Results from the Phase 1 study have been published, Winstedt el al. (2015) PLOS ONE 10(7).

*) EMA: In imlifidase for kidney transplantation we have filed for conditional approval after completion of phase 2. A confirmatory study would need to be executed in case of approval.

FDA: Discussion on path forward in the US is still ongoing.

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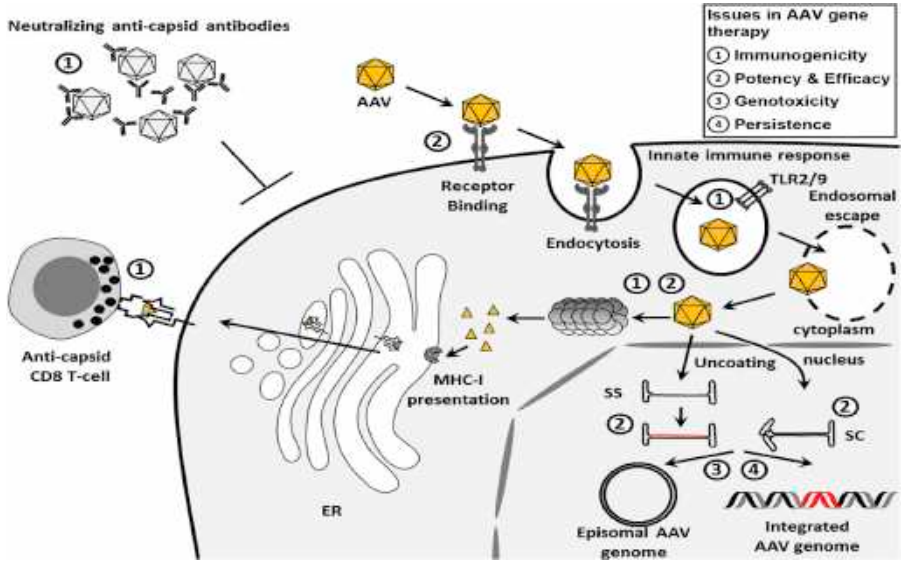
Exploring imlifidase in gene therapy as a potential pre-treatment to inactivate neutralizing antibodies

Nabs are immunological barriers in gene therapy

- Gene therapy programs may exclude up to 40% of patients from clinical studies and approved treatments due to presence of neutralizing antibodies[1]
- Most gene programs use viral vectors originating from Adeno-Associated Viruses (AAV) for gene insertions *in vivo*; however in many cases the human immune system have developed preformed neutralizing anti-AAV that prevents effective and safe use
- Today experimental protocols are used based on plasma-pheresis, or with immunosuppressants; however these protocols protocols have not demonstrated sufficient efficacy and safety
- 187 in vivo programs are ongoing in gene therapy including 73 clinical stage programs, while two *in vivo* gene therapy products have been approved by FDA (Luxturna from Spark Therapeutics and Zolgensma from Novartis)

Idea is to enable gene therapy despite Nabs



1 http://www.ijcem.com/files/ijcem0094241.pdf

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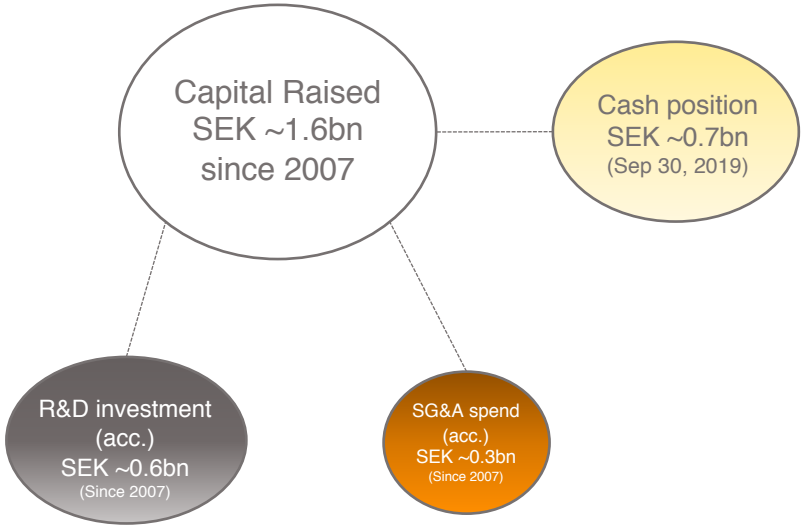
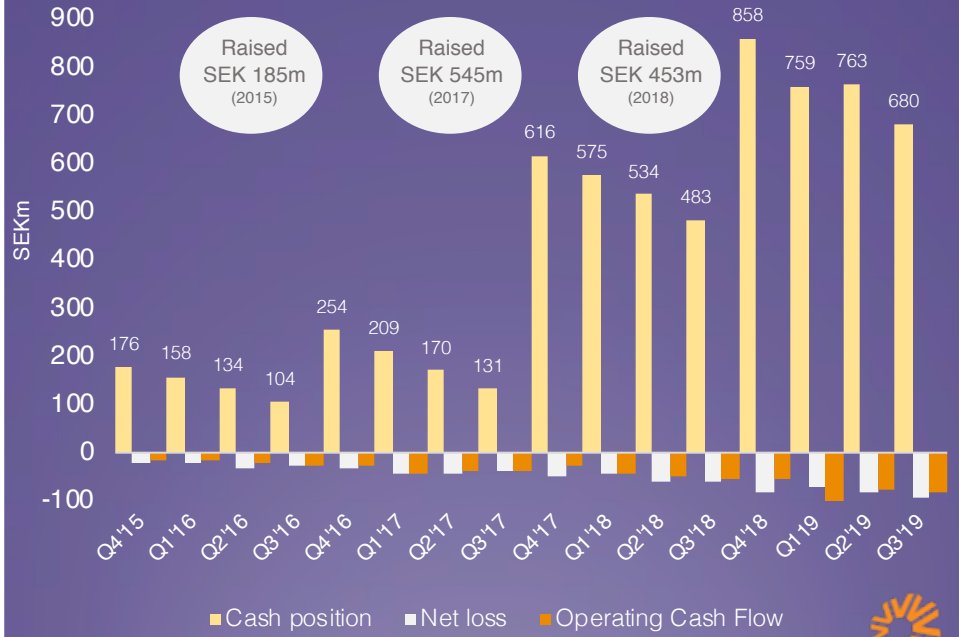
Hansa Biopharma is financed through 2020

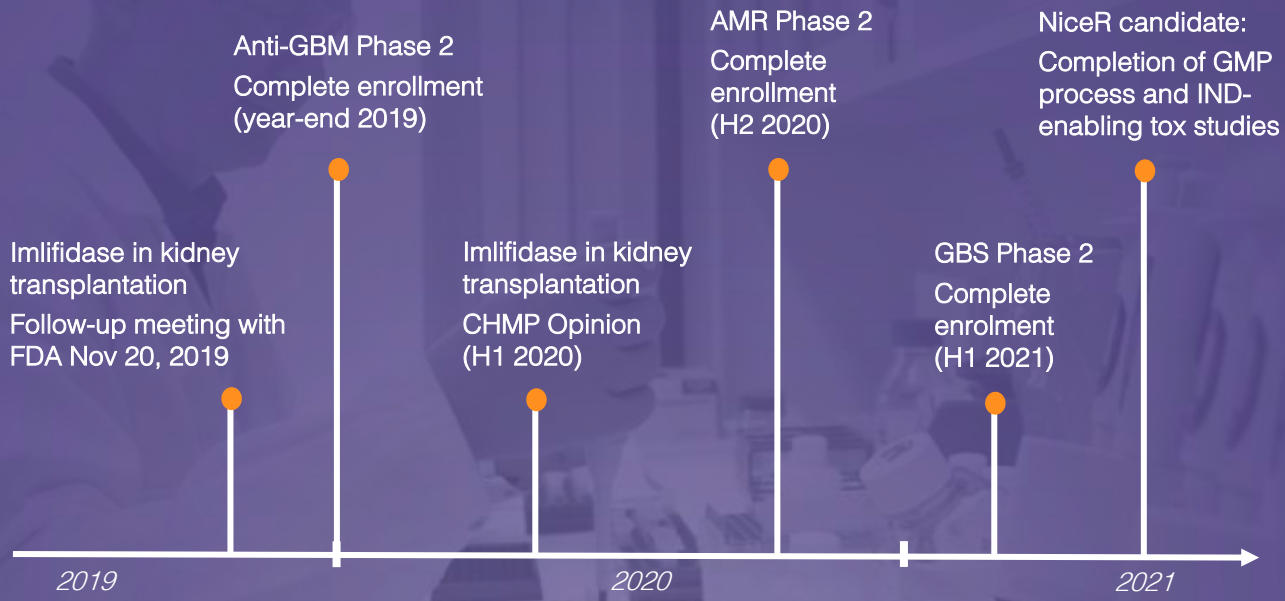
Significant capital raised since 2007



Cash position end of September 2019



Upcoming milestones

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Appendix

Completed and ongoing studies with imlifidase in kidney transplantation

STUDY	SUBJECTS/ COUNTRY	CLINICAL TRIALS.GOV ID	STUDY DESIGN	PRIMARY ENDPOINT	SECONDARY ENDPOINTS	STATUS	PUBLICATION
Study 01 Phase 1	29 subjects	NCT01802697 (2013/2014)	• Randomized placebo-controlled dose-escalation study with 29 (20 active plus 9 placebo) healthy subjects	• Safety and tolerability	• Efficacy in IgG cleavage, the pharmacokinetics (PK) and immunogenicity of imlifidase	Complete	PLOS ONE (2015)[1]
Study 02 Phase 2	8 subjects	NCT02224820	• Single-center, single-arm, open-label	• Dosing resulting in HLA-antibody reduction (MFI<1100)	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete	Lorant et al (2018) American Journal of Transplantation[2]
Study 03 Phase 2	10 subjects	NCT02475551	• Single-center, single-arm, open-label • No prior desensitization	• Safety: AEs, clinical laboratory tests, vital signs, ECGs	• Efficacy: HLA antibody reduction acceptable for transplantation (MFI <1100 as measured in SAB assay)	Complete	The New England Journal of Medicine (2017)[3]
Study 04 Phase 2	17 subjects	NCT024226684	• Investigator initiated study, Single-center, single-arm, open-label • All patients had prior desensitization with IVIG and/or plasmapheresis	• Assessment of efficacy in eliminating DSAs in DSA and flow cytometry positive, highly sensitized patients • Assessment of safety • Assessment of efficacy and kidney function	• Serum creatinine (0-6 months) • Proteinuria (0-6 months) • DSA at multiple timepoints posttransplant (day 0, D30, D90, D180)	Complete	The New England Journal of Medicine (2017)[3]
Study 06 "Highdes" Phase 2	18 subjects	NCT02790437	• Multicenter, multinational, single-arm, open-label Included pts who may have had prior unsuccessful desensitization or pts in whom it was unlikely to be effective	• Crossmatch conversion in DSA+ patients who have a positive XM test to their available LD or DD	• DSA reduction at multiple timepoints (2, 6, 24, 48 h after imlifidase) • Time to create negative CDC XM test and/or flow cytometry (FACS) XM test • Safety	Complete	Annals of Surgery (Lonze et al, only New York patients) Montgomery et al ATC abstract (2019)[4]
Long-term follow-up study	Up to 46 subjects	NCT03611621	• A prospective, observational long-term follow-up study of patients treated with imlifidase prior to kidney transplantation	• Long-term graft survival in patients who have undergone kidney transplantation after imlifidase administration	• Patient survival, kidney function, comorbidity, treatments and quality of life • Safety • DSA • Immunogenicity	Ongoing	

[1] Winstedt el al., "Complete Removal of Extracellular IgG Antibodies in a Randomized Dose Escalation Phase I Study with the Bacterial Enzyme IdeS – A Novel Therapeutic Opportunity", PLOS ONE 2015, 10(7)
[2] Lorant et al., "Safety, immunogenicity, pharmacokinetics and efficacy of degradation of anti-HLA antibodies by IdeS (imlifidase) in chronic kidney disease patients" Am J Transplant. 2018 Nov;18(11):2752-2762
[3] Jordan et al., "IgG Endopeptidase in Highly Sensitized Patients Undergoing Transplantation", N Engl J Med 2017;377:442-53.
[4] Montgomery et al., "Safety And Efficacy Of Imlifidase In Highly-sensitized Kidney Transplant Patients: Results From A Phase 2 Study" ATC Abstract, 2019

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Anti-GBM, a rare acute autoimmune disease affecting kidneys and lungs

2/3 of Anti-GBM patients lose their kidneys[2]

- Indication: Antibodies are directed against an antigen intrinsic to the glomerular basement membrane (GBM) causing acute injury of kidney and/or lung
- Anti-GBM affects one in a million annually (~900 worldwide[1,2]) with majority of patients lose kidneys[2], requiring chronic dialysis and kidney transplantation.
- The study is an open label investigator-initiated Phase 2 with Professor Mårten Segelmark at Linköping University Hospital as the sponsor and principal investigator
- The study is designed to evaluate the safety and tolerability of imlifidase in patients with severe anti-GBM disease on on top of standard care consisting of plasmapheresis, steroids and cyclophosphamide. 11 of 15 targeted patients enrolled
- Our Anti-GBM program obtained Orphan Drug designation from both FDA and European Commission (2018)

1 Kluth et al . J Am Soc Nephrol. 1999 Nov;10(11):2446-53
2 Hellmark et al. J Autoimmun. 2014 Feb-Mar;48-49:108-12

Long term graft survival is challenged by antibody mediated rejection post transplantation

There is no approved treatment for AMR

- Active antibody mediated rejection after transplantation occurs in 10-15% of kidney transplants[1] or ~ 3,200[2,3] patients annually[4] and is a significant challenge to long term graft survival
- Today's standard of care include plasma exchange, and treatment with steroid and IVIg. AMR patients not treated successfully risk graft failure, dialysis and return to the waitlist
- The AMR Phase 2 study is a randomized, open-label, multi-center, active control study designed to evaluate the safety and efficacy of imlifidase in eliminating donor specific antibodies (DSAs) in the treatment of active episodes of acute AMR in kidney transplant patients.
- The first patient out of targeted 30 patients was treated with imlifidase in Q3 2019. Enrollment is planned to take 12 months with an expected topline data read out 2H 2021

[1] Puttarajappa et al., Journal of Transplantation, 2012, Article ID 193724.
[2] Jordan et al., British Medical Bulletin, 2015, 114:113-125.
[3] http://www.irodat.org.
[4] Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

Guillain-Barré syndrome is an acute autoimmune attack on the peripheral nervous system

GBS can affect anyone at any age

- GBS is an acute autoimmune attack on the peripheral nervous system, which rapidly and progressively weakens extremities.
- Only parts of the patients fully recover from GBS, thus a high unmet medical need for new treatments; 40% lose strength and have pain while mortality is 3-7% mortality
- Addressable population of ~ 11,000[1] per year in 7MM[2]
- Current Standard of Care is treatment with IVIG or PLEX
- The new Phase 2 study is an open-label, single arm, multi-center study evaluating the safety, tolerability and efficacy of imlifidase in GBS patients in combination with standard of care intravenous immunoglobulin (IVIg)
- The GBS study aims at enrolling up to 30 patients at ten clinics in the EU over 18 months. Topline data is expected in H1 2022
- In 2018, the FDA granted Orphan Drug Designation to imlifidase for the treatment of GBS

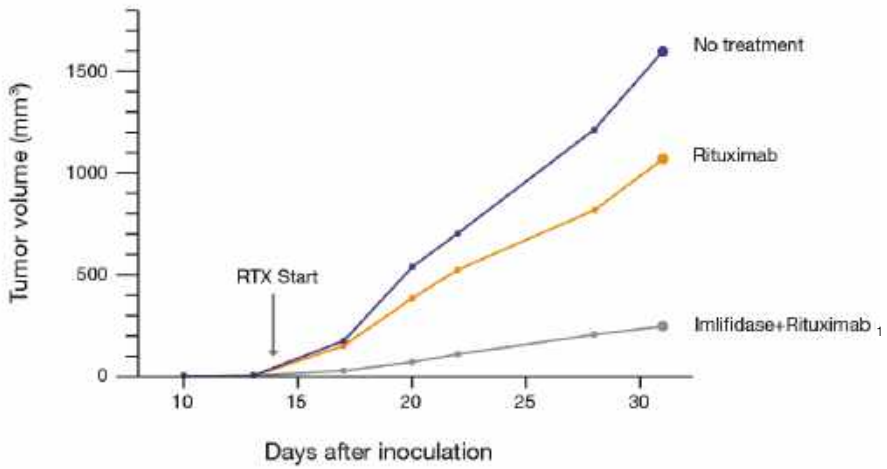
[1] McGrogan et al. Neuroepidemiology 2009;32(2):150-63.
[2] 7MM = Seven major markets – US, Germany, UK, France, Spain, Italy, and Japan

EnzE can potentially improve the therapeutic effect in oncology

Proof of concept demonstrated in vivo for mice

- Enzyme based antibody enhancement through pre-treatment
- The abundance of normal IgG in blood interferes with therapeutic monoclonal antibodies
- Pre-treatment with imlifidase / NiceR has potential to significantly potentiate antibody-based cancer therapies
- Suppressive effect of IVIg on effector cell function abrogated by imlifidase
- Imlifidase can significantly improve the therapeutic effect of rituximab

Mice with human IgG (~9mg/mL)

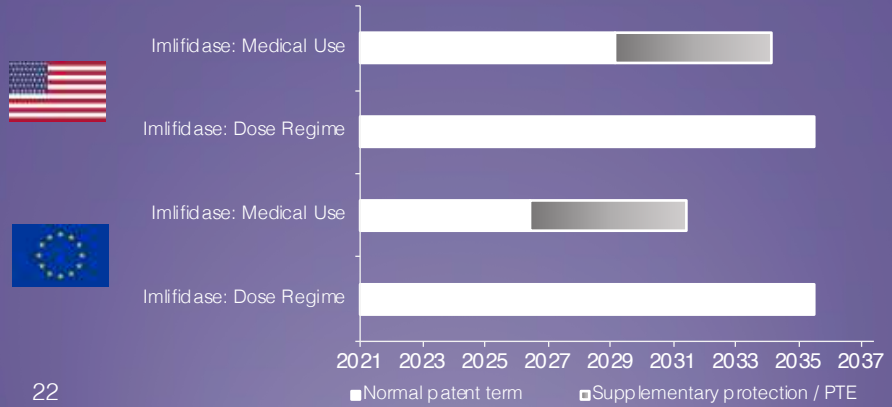


[1] Järnum et al. Mol Cancer Ther 2017;16:1887-1897

Strong technology protection through patents and orphan drug designation

Patent coverage out to 2030/35 in key markets

- Hansa Biopharma's portfolio consist of 11 separate patent families incl. 7 patent families in relations to the use of imlifidase (granted/pending)
- Patents cover use of isolated imlifidase in:



Orphan drug designation

- Orphan drug designation is granted to drugs intended for rare diseases (affecting max 5 patients in 10,000 persons in EU or affecting less than 200,000 patients in the US.
- Designation provides development and commercial incentives incl. 10 years market exclusivity in EU and 7 years in the US

EMA

Orphan drug designation

- Imlifidase for the prevention of graft rejection following solid organ transplantation (2017)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

FDA

Orphan drug designation

- Imlifidase for the prevention of antibody-mediated organ rejection in solid organ transplantation (2015)
- Imlifidase for the treatment of Guillian-Barré Syndrome (2018)
- Imlifidase for the treatment of the rare and acute disease anti-GBM (2018)

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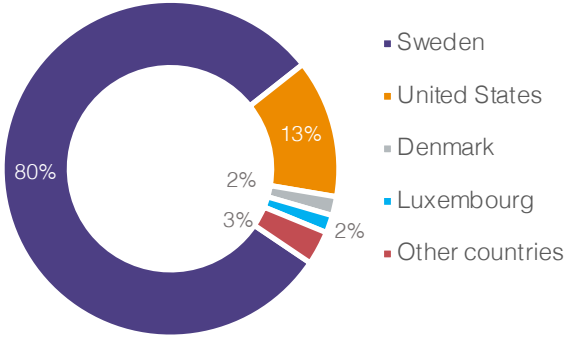
Ownership in Hansa Biopharma

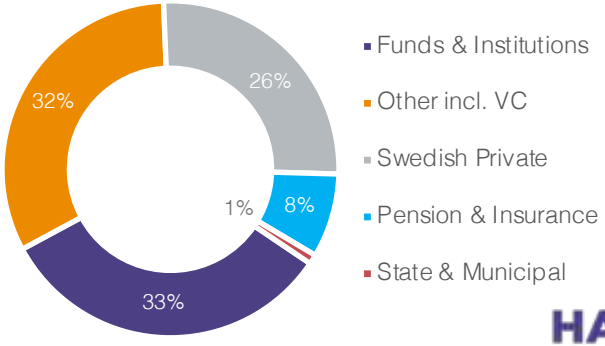
Top 10 ownership as per September 30, 2019

Name	No. of shares	Ownership in pct.
NXT2B	5 757 659	14.4
Invesco	2 659 217	6.6
Thomas Olausson	1 617 654	4.0
Handelsbanken Funds	1 511 766	3.8
Avanza Pension	1 309 565	3.3
Fourth Swedish National Pension Fund	1 067 044	2.7
Norron Funds	959 557	2.4
AFA Insurance	953 734	2.4
Vanguard	909 375	2.3
Gladiator	900 000	2.2
Other	22 380 536	55.9
Outstanding shares in total	40 026 107	100.0

Ownership by country



Ownership by type



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Visit our new web site
www.hansabiopharma.com

Calendar

Oct 31, 2019	Interim report Jan – Sep 2019
Nov 4-7, 2019	NDRS MorganStanley, US
Nov 12, 2019	Bryan Garnier Healthcare Conference, Paris
Nov 14-15, 2019	NDRS Kempen, Amsterdam and Zurich
Nov 15, 2019	NDRS Carnegie, Stockholm
Nov 19, 2019	Redeye Lifescience Conference, Stockholm
Nov 20, 2019	Jefferies Global Healthcare Conference, London
Dec 4, 2019	Evercore Annual Health CONx Conf, Boston
Dec 5, 2019	DNB Nordic-American Life Science Conf, NYC
Jan 8, 2020	SEB Nordic Seminar, Copenhagen
Jan 12-15, 2020	JPM Week, San Francisco
Feb 6, 2020	Interim Report Oct-Dec 2019
Mar 4, 2020	Carnegie Nordic Healthcare Seminar, Stockholm
Apr 2, 2020	Annual Report 2019
Apr 28, 2020	Interim Report Jan-Mar 2020

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